

Remarks

Claims 50-66 were pending in the application. Claims 54-55 and 57 have been cancelled. New claims 67-72 have been added. Claims 50-53, 56, 58-60, 62-65 have been amended.

Claims 50-53, 56 and 58-72 remain for examination.

Claim objection – spelling

The objection to the spelling error in claim 50 was rendered moot by deleting the word at issue.

Claim rejections - § 112, first paragraph

Various claims were rejected under 35 U.S.C. § 112, first paragraph, as failing to enable one skilled in the art to make and use the claimed invention. Applicant has amended the sole independent claim 50 by deleting “preventing” and reciting “treating a local inflammatory condition by topical application.” These amendments are believed to overcome the rejections, consistent with the Examiner’s comments that it would be more appropriate to limit the claims to a method of treating (and delete preventing, see e.g., pages 5 and 7 of the Office Action).

In addition, the skilled person would have a reasonable expectation of successfully treating a local inflammatory condition by topical application, based upon the disclosed examples and other description in the specification. These amendments are believed to overcome the Examiner’s broad reading of the prior claim language as including the treatment of all inflammatory conditions in a mammalian body (such as asthma attacks, inflammation of the pancreas during bouts of pancreatitis, or inflammation of the brain caused by encephalopathy (page 6 of the Office Action)).

Claims 51 and 55 were rejected regarding use of the term “derivatives thereof,” the Examiner asserting that a great variety of compounds was included in the scope thereof, which can be interpreted to even include elemental carbon, nitrogen and hydrogen as derivatives of the recited class of compounds, and that Applicant had not

identified a chemical structure or function such that one of ordinary skill in the art could understand what is meant by derivatives.

Applicant respectfully asserts that Applicant's limited use of the term derivatives is proper and there is a clear disclosure in the specification of what is meant, including:

a) the term "enamel matrix derivative" has previously been described in the patent literature and is thus familiar to persons of ordinary skill in the art (see e.g., the referenced public patents identified in paragraphs [0003, 0094 and 0104] of the specification);

b) an extensive definition of "Enamel Matrix, Enamel Matrix Derivatives and Enamel Matrix Proteins" is set forth in paragraphs [0092-0114] of the specification, which includes beginning at paragraph [0095] the specific disclosure:

In the present context, enamel matrix derivatives are derivatives of enamel matrix which include one or several of enamel matrix proteins or parts of such proteins, produced naturally by alternate splicing or processing or by either enzymatic or chemical cleavage of a natural length protein, or by synthesis of polypeptides in vitro or in vivo (recombinant DNA methods or cultivation of diploid cells). Enamel matrix protein derivatives also include enamel matrix related polypeptides or proteins. The polypeptides or proteins may be bound to a suitable biodegradable carrier molecule, such as polyamino acids or polysaccharides, or combinations thereof. Furthermore, the term enamel matrix derivatives also encompasses synthetic analogous substances.

and is followed by a detailed description with examples of such polypeptides or proteins, their molecular weights, relative weight fraction in the composition, and amino acid sequences [0096-0114];

c) a description of the "Physico-Chemical Properties of Enamel Matrix, Enamel Matrix Derivatives and Enamel Matrix Proteins" beginning at paragraph [0115] and reciting in the following paragraph [00116]:

In general the enamel matrix, enamel matrix derivatives and enamel matrix proteins are hydrophobic substances, i.e., less soluble in water especially at increased temperatures. In general, these proteins are soluble at non-physiological pH values and at a low temperature such as about 4-20° C., while they will aggregate and precipitate at body temperature (35-37°C.) and neutral pH.

d) identification of a commercially available enamel matrix derivative product, e.g., EMDOGAIN® [0098]; and

e) an Experimental Section with 15 examples illustrating preparation and use of an enamel matrix derivative [0218-0424].

Thus, Applicant respectfully asserts that based on the previously published patent literature, commercially available product, and Applicant's extensive specification, the skilled person has a clear understanding of what is meant by "derivatives" of the recited group of active enamel compounds.

Claim rejections —35 U.S.C. § 112, second paragraph

The objection to claims 51 and 55 in regard to use of the term "derivatives thereof" as being indefinite, is overcome for the reasons previously set forth.

The objection to the multiplicity of ranges in claims 52-53 has been overcome by adding new claims 67-72 with the alternative ranges. The objection to claim 55 is moot as the claim has been cancelled.

The objection to the parenthetical in claim 51 has been rendered moot by cancelling the same from claim 51. Claim 56 now includes this subject matter.

Claim rejections — 35 U.S.C. § 102

The claims are rejected as anticipated by Hammarstrom et al. U.S. Patent 5,071,958. However, in view of the Examiner's finding that "the method of Hammarstrom et al. cannot be considered to 'treat' inflammatory conditions" (page 11),

and Applicant's amendment of the claims limiting them to a method of treating (and deleting a method of preventing), it is believed that all claims are now in condition for allowance.

Double patenting

Various claim sets were rejected for non-statutory obviousness-type double patenting. In view of the above amendments to the claims and deletion of prior claims 54, 55 and 57, it is believed that the double patenting objection has been overcome. The present claims now recite a method of treating a local inflammatory condition as previously described.

RECONSIDERATION

It is believed that all claims of the present application are now in condition for allowance.

Reconsideration of this application is respectfully requested. If the Examiner believes that a teleconference would expedite prosecution of the present application the Examiner is invited to call the Applicant's undersigned attorney at the Examiner's earliest convenience.

Any amendments or cancellation or submissions with respect to the claims herein is made without prejudice and is not an admission that said canceled or amended or otherwise affected subject matter is not patentable. Applicant reserves the right to pursue canceled or amended subject matter in one or more continuation, divisional or continuation-in-part applications.

To the extent that Applicant has not addressed one or more assertions of the Examiner because the foregoing response is sufficient, this is not an admission by Applicant as to the accuracy of such assertions.

Please grant any extensions of time required to enter this response and charge any fees in addition to fees submitted herewith that may be required to enter/allow this response and any accompanying papers to our deposit account 02-3038 and credit any overpayments thereto.

Respectfully submitted

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